

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

KERRY LANGSTAFF, et al

Respondents,

v.

**ALLEN A. MITCHELL, M.D.,
SAMUEL M. LESKO, M.D., and
TRUSTEES OF BOSTON UNIVERSITY**

Petitioners.

§ **Civil Action No. 04-MBD**

§

§ **Related Civil Action:**

§ **United States District Court for the
§ Northern District of California, San
§ Jose Division**

§ **Civil Action No. 03-CV-01116**

§ **KERRY LANGSTAFF, et al vs.**

§ **MCNEIL CONSUMER &**

§ **SPECIALITY**

§ **PHARMACEUTICALS, et al**

§

§

**RESPONDENT'S REPSONSE TO PETITIONER'S MOTION TO QUASH
DEPOSITION SUBPOENAS AND SUBPOENAS DUCES TECUM PURSUANT
TO FED. R. CIV. P. 45 (c) (3) (A) and (B)**

TO THE HONORABLE JUDGE OF SAID COURT:

COME NOW, Respondents, by and through their attorney of record, and files this Response to Petitioners Motion To Quash Deposition Subpoenas and Subpoenas Duces Tecum Pursuant To FED. R. CIV. P. 45 (c) (3) (A) and (B). Respondents attach a Memorandum citing supporting authoririties.

REQUEST FOR ORAL ARGUMENT

Respondents wish to be heard by the Court regarding this matter as expeditiously as possible as the deposition petitioner seeks to quash are scheduled on May 24th and 27th 2004 to comply with discovery deadlines in Respondents underlying suit filed in the United States District Court for the Northern District of California and believe that oral argument would assist the Court.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

KERRY LANGSTAFF, et al

Respondents,

v.

ALLEN A. MITCHELL, M.D.,
SAMUEL M. LESKO, M.D., and
TRUSTEES OF BOSTON UNIVERSITY

Petitioners.

§ Civil Action No. 04-MBD 10/37
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§ Related Civil Action:
§ United States District Court for the
§ Northern District of California, San
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§ KERRY LANGSTAFF, et al vs.
§ MCNEIL CONSUMER &
§ SPECIALITY
§ PHARMACEUTICALS, et al
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**RESPONDENTS' MEMORANDUM IN SUPPORT OF THEIR
RESPONSE TO PETITIONERS' MOTION TO QUASH DEPOSITION
SUBPOENAS AND SUBPOENAS DUCES TECUM PURSUANT TO
FED. R. CIV. P. 45(c)(3)(A) and (B)**

TO THE HONORABLE JUDGE OF SAID COURT:

COME NOW, Respondents, by and through their attorney of record, and files this Memorandum in Support of their Response to Petitioners' Motion to Quash Deposition Subpoenas and Subpoenas Duces Tecum Pursuant to Fed. R. Civ. P. 45(c)(3)(A) and (B). Respondents served subpoenas on Drs. Allen Mitchell and Samuel Lesko, employees of the Slone Epidemiology Center¹ at Boston University (hereinafter "Boston University") at the time of the Boston University Fever Study, to be deposed on May 26 and 27, 2004. Respondents seek to depose both doctors and to require production of certain documents as such discovery is crucial and goes to the heart of Respondents suit against McNeil Consumer & Speciality Pharmaceuticals (hereinafter "McNeil") and Johnson & Johnson filed in the United States District Court for the Northern District of California.

¹ Dr. Mitchell is the Director of the Slone Epidemiology Center. Dr. Lesko was the senior investigator until 2000.

I. BACKGROUND

This is a pharmaceutical products liability case involving the injury and untimely death of 8-year-old Kaitlyn Sierra Langstaff from Stevens-Johnson Syndrome/Toxic Epidermal Necrolysis (SJS/TEN) caused by an adverse reaction to Children's Motrin. Defendants McNeil and Johnson & Johnson relied upon the results from the Boston University Fever Study, which Drs. Mitchell and Lesko have crucial information regarding, to support the approval of the over the counter marketing of Children's Motrin. This study was the critical safety study that McNeil used to claim the safety of ibuprofen in the treatment of fever in children in the U.S. Accordingly, Respondents seek to depose and obtain documents, pursuant to subpoenas duces tecum, from Drs. Mitchell and Lesko.

II. ARGUMENT

A. Legal Standard

Rule 45 of the Federal Rules of Civil Procedure establishes the same broad scope of discovery to a non-party that exists to the parties involved in the litigation. *United States ex rel. Schwartz v. TRW, Inc.*, 211 F.R.D. 388, 392 (C.D. Cal. 2002). Rule 45(d) adopts the standards set out in Rule 26(b)(1), which permits discovery of any non-privileged matter relevant to the subject matter even if it would be inadmissible at trial, so long as it would appear reasonably calculated to lead to the discovery of admissible evidence. *Anker v. G.D. Searle & Co.*, 126 F.R.D. 515, 518 (M.D.N.C. 1989). "Courts, whose only connection with the controversy is to rule on discovery motions for the case which is pending in another district, should be cautious in restricting discovery because such 'ancillary' courts will find it more difficult to have a complete understanding of the case and what is relevant and, therefore, should err on the side of permitting discovery." *Id.* (citing *Truswal Systems Corp. v. Hydro-Air Engineering, Inc.*, 813 F.2d 1207, 1211-12 (Fed. Cir. 1987); *Heat and Control, Inc. v. Hester Industries, Inc.*, 785 F.2d 1017, 1024

(Fed. Cir. 1986)). Relevance for discovery purposes is given very broad meaning. *Allen v. Howmedica Leibinger, Inc.*, 190 F.R.D. 518, 521 (W.D.Tenn.1999).

A basic premise in American jurisprudence is that the court has the right to evidence from every individual unless protected by constitutional, statutory, or common law privileges. *Branzburg v. Hayes*, 408 U.S. 665, 688, 92 S.Ct. 2646, 2660, 33 L.Ed.2d 626 (1972). The weight of federal authority and case law holds that a non-party, involuntary expert or non-fact witness does not have a right to decline to give testimony or produce documents even though the witness will be compelled to divulge matters which are normally considered confidential, sensitive, proprietary, or which pertain to his expertise or special skill. *Anker*, 126 F.R.D. at 520 (citing *Truswal Systems Corp.*, 813 F.2d 1207; *Heat and Control, Inc.*, 785 F.2d 1017; *Deitchman*, 740 F.2d 556; *Kaufman v. Edelstein*, 539 F.2d 811; and Annotation, *Expert Testimony Refusal*, 50 A.L.R.4th 680 (1986)).

B. Boston University Has Failed to Present Any Valid Reason Under Rule 45 to Quash the Depositions of Drs. Mitchell and Lesko

Rule 45 provides four bases under which a subpoena can be quashed or modified by the Court. *See* Fed. R. Civ. P. 45(c)(3)(A). Boston University does not assert *any* of these as a basis for its Motion to Quash oral deposition. Thus, the Motion should be denied on its face, as Respondents have complied with all requirements of the Rules of Civil Procedure. For the sake of a complete response for the Court's consideration, Respondents will assume that Boston University contends that the subpoenas subject an "undue burden" on Drs. Mitchell and Klesko. *See* Fed. R. Civ. P. 45(c)(3)(A)(iv). If the subpoenas could be conceived as constituting an undue burden, then in order to justify quash or modification, the subpoena must require one of the three enumerated justifications under Rule 45(c)(3)(B). Boston University asserts that the subpoenas require disclosure of an "unretained expert's opinion or information not describing specific events or occurrences in dispute and resulting from the expert's study made not at the request of any

party.” See Fed. R. Civ. P. 45(c)(3)(B)(ii). Boston University makes this contention even though it admits that Defendant McNeil requested that Drs. Mitchell and Lesko conduct the Boston University Fever Study. Obviously, this provision of the Rules affords Boston University no basis to quash. It is the only justification under Rule 45(c)(3)(B) that Boston University provides in its Motion.

Boston University asserts, without authority, that Respondents have the burden to show a “substantial need for Drs. Mitchell and Lesko’s testimony.” See Motion to Quash at 9. It is, however, the burden of Boston University to make a facially valid motion through the proper provisions of Rule 45. Boston University has not made one even seemingly valid contention under Rule 45(c)(3)(B) to avail itself of quash or modification. Boston University simply attempts to lead the Court to the factors dealing with undue hardship enumerated in *Kaufman v. Edelstein*. 539 F.2d 811, 822 (2d Cir. 1976). The Kaufman factors go to the first hurdle of Rule 45(c)(3)(A). See *Anker*, 126 F.R.D. at 521. Without satisfying Rule 45(c)(3)(B), there is no reason for the Court to undertake the task of analyzing these factors, however, consideration of the *Kaufman* factors shows that the weight of Respondents need for discovery is much greater than the hardship created.

The *Kaufman* Court created a non-exclusive list of factors for the trial court to consider in determining whether to compel the testimony of a non-party expert. *Kaufman*, 539 F.2d at 822. The factors listed were “the degree to which the expert is being called because of his knowledge of facts relevant to the case rather than in order to give opinion testimony; the difference between testifying to a previously formed or expressed opinion and forming a new one; the possibility that, for other reasons, the witness is a unique expert; the extent to which the calling party is able to show the unlikelihood that any comparable witness will willingly testify; the degree to which the witness is able to show that he has been oppressed by having continually to testify.” *Id.* The key factor is that Drs. Mitchell and Lesko are unique witnesses. As the individuals who conducted and controlled the study, requested by Defendant McNeil, which was the basis for

FDA approval for over the counter use of ibuprofen for children, Drs. Mitchell and Lesko are the only source to answer Respondents questions regarding the Boston University Fever Study. *See id.* at 821; *In re Cary*, 167 B.R. 163, 167 (Bankr. W.D. Mo. 1994). They know the most facts regarding the research and analysis of skin-related reactions. They would be testifying about the research that they already performed and formed opinions. They presumably possess insight which was not relayed in any published text. And they have not been oppressed as they have never testified before, and there is no indication of a deluge of subpoenas. Boston University contends that Drs. Mitchell and Lesko published articles are sufficient for Respondents. However, in its Motion Boston University misleads the Court by stating that “Kaitlyn Langstaff suffered an event that was not identified in any child in the Boston University Fever Study.” *See Motion to Quash* at 6. Although still reviewing documentation from the Study that has been received from Defendant McNeil, Respondents have found direct diagnosis of Stevens-Johnson Syndrome from the doctors participating in the Study. Furthermore, Drs. Mitchell and Lesko published an article, *see Exhibit A*, indicating that three children in the study suffered from Erythema Multiforme, which is often diagnosed instead of Stevens-Johnson Syndrome as both disorders cause similar skin reactions. These discrepancies can only be addressed by those who conducted the research. The *Kaufman* factors weigh in favor of Respondents.

B. Boston University Has Failed to Present to the Court Why It Is Substantially Burdened to Justify that the Subpoenas Duces Tecum Be Quashed Under Rule 45

Boston University makes numerous objections to the subpoena duces tecum contending that Respondent’s discovery against Defendant McNeil in the underlying suit makes these requests burdensome and repetitive. Boston University also asserts that Respondents seek irrelevant documents. Respondents have exhausted discovery against Defendant McNeil as it has pointed to Boston University as the source of materials. *See Exhibit B*. Respondents simply seek to obtain relevant discovery. In particular, Defendant McNeil claims to have no correspondence

documents in its possession relating to the Boston Fever Study. *See* Exhibits B and C. This contention is made to Respondents even though Defendant McNeil served on the committee for serious adverse events. Thus, any material could represent an admission against interest. In regards to the clinical data from the advisory committee meetings, Defendant McNeil has produced vague documentation, which consistently mentions other meetings, which have not been produced to Petitioner. *Id.* Defendant McNeil asserts that it does not possess these minutes, but Boston University does. *Id.* Respondents merely seek to discover the truth and be able to prepare for their case with all relevant documents. Boston University has produced no evidence and simply made conclusory statements regarding its burden. *See Hussey v. State Farm Lloyds Ins. Co.*, 216 F.R.D. 591, 595 (E.D. Tex. 2003). It is, however, an appropriate avenue for Respondents to seek documentation. *See* Fed. R. Civ. P. 34(c) and 45(a)(1)(C). A Court should only not honor a subpoena if "it is palpable that the evidence sought can have no possible bearing upon the issues." *See Hercules Powder Co. v. Rohm & Hass Co.*, 3 F.R.D. 302, 304 (D.Del.1943). The subpoena duces tecum served on Drs. Mitchell and Lesko clearly seeks documentation that bears directly on Respondents law suit against Defendant McNeil. *See* Exhibit B.

Boston University asserts that Respondents seek discovery already produced by Defendant McNeil. However, Respondents would not seek discovery, nor spend the time and resources required, from a third-party if Respondents had obtained the requested discovery from Defendant McNeil. Respondents have exhausted all documentation that McNeil claims to possess. *See* Exhibits B and C. Respondents also do not seek to breach the confidentiality of the study participants. Respondents have no interest in the identity of study participants, but merely the results and reactions that happened to participants. Accordingly, Respondents cannot fathom how compliance with the subpoenas would quell efforts to attract volunteers for future research studies. Respondents would also like to note that they are simply individuals who have suffered through a tremendous tragedy. Respondents are involved in litigation stemming from the death

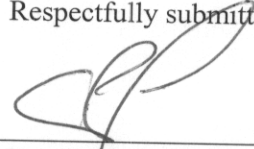
of a young girl. In determining if disclosure would be harmful, the Court must consider "not the injury that would be caused by public disclosure, but the injury that would result from disclosure under an appropriate protective order." *Coca Cola Bottling Co. v. The Coca Cola Co.*, 107 F.R.D. 288, 293 (D.Del.1985). Disclosure to a competitor is presumed to be more harmful than disclosure to a non-competitor. *Id.* Thus, Respondents have no interest in "trade secrets" or "commercial information" which are the basis of Rule 45(c)(3)(B). Respondents merely seek to discover the knowledge, which was had, or should have been had, of the dangers of skin afflictions from the ingestion of ibuprofen and whether or not there was concealment of these dangers or bias in the studies. *See Hussey*, 216 F.R.D. at 594. With this in mind, it is clear to see Respondents are entitled to the documentation requested in the subpoenas duces tecum served on Drs. Mitchell and Lesko.

III. CONCLUSION

Respondents are entitled to discovery from nonparties, such as Drs. Mitchell and Lesko. *See Fed. R. Civ. P. 34(c) and 45(a)(1)(C)*. Respondents seek to depose both doctors and to require production of certain documents as such discovery is crucial and goes to the heart of Respondents suit against Defendant McNeil. Boston University fails to justify its Motion to Quash. Accordingly, Petitioners Motion to Quash should be denied in its entirety.

WHEREFORE, PREMISES CONSIDERED, Respondents respectfully request this Court deny Petitioners Motion to Quash and grant Respondents any and all other relief to which they may be justly entitled.

Respectfully submitted,



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CERTIFICATE OF SERVICE

I certify that the foregoing Motion to Compel and Memorandum in Support was served on Boston University and all counsel of record via facsimile and U.S. Mail on the ____ day of May, 2004.


Edward Paul Coady

REQUEST FOR ORAL ARGUMENT

I certify that Petitioners wish to be heard by the Court regarding this matter as expeditiously as possible as the deposition petitioner seeks to quash are scheduled on May 24th and 27th 2004 to comply with discovery deadlines in Respondents underlying suit filed in the United States District Court for the Northern District of California and believe that oral argument would assist the Court.


Edward Paul Coady